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Display Date 10-26-99
Publication Date 10-27-99
Certifier SNReese

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 **CFR Part 26**

[Docket No. 98S–1064]

Mutual Recognition of Pharmaceutical Good Manufacturing Practices Annex; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Announcement of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss the progress of implementing the Mutual Recognition Agreement (MRA) Pharmaceutical Good Manufacturing Practices (GMP's) Annex between the United States and the European Community (EC). FDA is inviting interested persons, including industry, trade, and consumer groups.

DATES: The meeting will be held on Wednesday, December 8, 1999, from 9 a.m. to 1 p.m. Registration and requests to make an oral presentation should be received by Monday, November 22, 1999.

ADDRESSES: The meeting will be held in the Center for Drug Evaluation and Research Advisory Committee Conference Room, 5630 Fishers Lane, Rockville, MD 20857. To register and request time for an oral presentation, send or fax written material to the listed contact person.

FOR FURTHER INFORMATION CONTACT: Charles A. Gaylord, Office of International and Constituent Relations (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0909, FAX 301–443–0235.

SUPPLEMENTARY INFORMATION:

I. Background

Regulationsimplementing the MRA were published as a final rule in the **Federal Register** of November 6, 1998 (63 FR 60122). In the preamble to the final rule, FDA stated that it plans to hold periodic meetings with interested parties and make public summaries of key meetings held with its EU counterparts concerning implementation of the MRA (63 FR 60122 and 60127). The regulations were codified in part 26 (21 CFR part 26). FDA established Docket No. 98S–1064 to share public information concerning the implementation of part 26 (64 FR 11376, March 9, 1999). FDA has and will continue to make information concerning the implementation of the MRA and part 26 available to the public on FDA's web site at http://www.fda.gov/oia/homepage.htm (International section).

II. The Public Meeting

The December 8, 1999, meeting is the first public meeting FDA has held on the Pharmaceutical GMP's Annex to the MRA since the final rule published. The purpose of the meeting is to provide information concerning FDA activities related to the implementation of the MRA Pharmaceutical GMP's Annex (covering human and animal drug and human biological products) and to provide an opportunity to hear comments and address concerns from interested members of the public.

The meeting agenda will include: (1) FDA presentations with a summary of the progress made in the implementation of the Pharmaceutical GMP's Annex; discussion of the two-way alert system; public access to information; the process used to determine the equivalence of the regulatory systems for pharmaceutical GMP's and work plan, (2) outside presentations, and (3) panel discussion; question and answer session.

When submitting a request for time for an oral presentation at the meeting, please indicate your topic, provide a presentation outline, and identify any presentation needs (an overhead projector, slide projector, etc.). Time allowed for accepted presenters will depend on the number of presentation requests. Registration information (including name, title, firm name, address,

telephone, and fax number) and requests for presentation (including topic and outline) should be submitted to the listed contact person by November 22, 1999. Space is limited, therefore, interested parties are encouraged to register early. Special accommodations due to disability should be submitted at least 7 days in advance.

Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: 10/19/99
October 19, 1999

Margaret M. Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 99–???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F

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Sybelle N. Reese